

REMARKS

The Official Action of July 29, 2008, and the prior art cited and applied therein have been carefully reviewed. The claims in the application are now only claims 7, 14 and 15, and these claims define patentable subject matter warranting their allowance. Applicants respectfully request favorable reconsideration and allowance.

Acknowledgement by the PTO of the receipt of applicants' papers filed under Section 119 is noted.

The restriction requirement has been maintained and in effect made final. Applicants now accept the restriction requirement and consequently have deleted the non-elected claims without prejudice to applicants' rights to proceed with a divisional application without any penalty whatsoever, applicants in such a case relying on Sections 121, 120 and 119.

The objection to the specification has been noted, and the URL has been deleted as required.

The abstract has been objected to as apparently not having been written in proper idiomatic English, and

appropriate correction has been required. The objection and requirement are respectfully traversed.

Applicants see nothing wrong with the abstract and nothing in particular has been pointed out as being not in proper idiomatic English.

Withdrawal of the objection and requirement is respectfully requested.

Claims 1, 14 and 15 have been objected to because of certain recitations, and the examiner has made some helpful suggestions to improve the form of the claims. These suggestions have been adopted in the rewriting of claim 7 as the main claim in this application. In particular the following amendments have been made in claim 7:

Line 1, the phrase "A polypeptide" is changed to "An isolated polypeptide".

Lines 2-5, the phrase "with which a dsRNA ... can be obtained," is changed (lines 6 and 7) to "wherein degradation products of dsRNA with said polypeptide function in RNA interference as a siRNA". This is supported by the description in page 17, lines 14-21 of the original English translation text.

Lines 10-11, i.e., in (b), the phrase "in which one or ... or added in" is changed (line 13) to "having an

identity of at least 95% to". This is supported by the description at page 18, lines 15-20 of the original English translation text.

Lines 15-16, i.e., in (c), the phrase "nucleotide sequence" is changed to "polynucleotide".

Line 17, i.e., in (c), between "to" and "the nucleotide", "a polynucleotide having" is added.

Line 18, i.e., in (c), "under stringent conditions" is replaced by what it means, based on the description in page 19, lines 1 to 11 of the original English translation text.

Withdrawal of the objection is in order and is respectfully requested.

Claims 1-8 have been rejected under Section 101 as being allegedly directed to non-statutory subject matter. The rejection is respectfully traversed.

Nevertheless, the examiner has helpfully how this rejection may be overcome, and such suggestion has been adopted.

Withdrawal of the rejection is in order and is respectfully request.

Of the examined claims, claims 1-6 and 8 have been deleted with out prejudice to applicants' rights to pursue

such claims or other claims broader than present claim 7, if applicants choose to do so, in a continuing application.

Claims 2-4 and 7 have been rejected under the second paragraph of Section 112. The rejection is respectfully traversed.

Claim 7, which is now the only main claim, now calls for:

an isolated polypeptide containing the amino acid sequence of SEQ ID NO: 4 (claim 7(a)),

an isolated polypeptide containing an amino acid sequence having an identity of at least 950/0 to the amino acid sequence of SEQ ID NO: 4 (claim 7(b)), or

an isolated polypeptide containing amino acid sequence encoded by a polynucleotide capable of hybridizing to a polynucleotide having the nucleotide sequence of SEQ ID NO: 1 under stringent conditions (claim 7(c)), wherein the stringent conditions are specified.

"Tm" in claim 7(c) is described in Sambrook et al., Molecular cloning, A laboratory manual, 3rd edition, 2001, Cold Spring Harbor Laboratory Press, and can be calculated by the following equation well known to the person skilled in the art:

$$Tm = 81.5^{\circ}\text{C} - 16.6(\log_{10}[\text{Na}^+]) + 0.41(\%G+C) - 0.63(\%\text{formamide}) - (600/1)$$
$$96.89 = 81.5 - 16.6(\log_{10}0.99) + 0.41(267/678*100) - 0.63*0 - (600/678)$$

According to the above T_m, "T_m-25°C" is calculated as being 71.89. A person skilled in the art can readily understand that the specified conditions are stringent conditions.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 1-8, 14 and 15 have been rejected under the first paragraph of Section 112 as failing to comply with the written description requirement, and as lacking enablement. These rejections are respectfully traversed.

First, most of the so rejected claims are original and thus meet the written description requirement in that regard.

The rejection states that there is no structural feature which is representative of all the members of the genus of proteins recited in the claims (page 9, lines 3-6 of the Official Action). However, it is well known in the art that a polypeptide having an identity of at least 95° to the amino acid sequence of SEQ ID NO: 4 or a polypeptide encoded by a polynucleotide capable of hybridizing to a polynucleotide having the nucleotide sequence of SEQ ID NO: 1 under stringent conditions has the same characteristics as those of the polypeptide having the amino acid sequence of SEQ ID NO: 4 with a high probability. A case where a polypeptide having

one substitution of an amino acid residue or having an identity of 95% would have a different activity is such a quite exceptional case that it would become a theme of a treatise.

Applicants believe and submit that a person skilled in the art can readily confirm that a particular polypeptide is not included in the claimed polypeptide by confirming its RNase III activity and degradation products according to the description in page 42, line 1 to page 44, line 15 of the original English translation text.

Since there are many US patents which have been granted under similar situations as that in the present application, a precedent has been set, and it is art accepted, whereby it is clear that a person skilled in the art can carry out the claimed invention based on the disclosure of the present specification without undue experiment.

Withdrawal of the rejections is in order and is respectfully requested.

Claim 1-8 and 14 (but not claim 15) have been rejected under Section 102 as being anticipated by Heidelberg et al, Reference X (Heidelberg). This rejection is respectfully traversed.

As claims 1-6 and 8 are no longer pending, applicants need not address the rejection at the present time as it applies to these claims, applicants reserving the right to pursue such claims or other broader claims, if applicants choose to do so, in a continuing application, without any penalty whatsoever, applicants in such a case relying on Sections 120 and 119.

As noted above, claim 7, which is now the sole and only independent claim, is directed to:

an isolated polypeptide containing the amino acid sequence of SEQ ID NO: 4 (claim 7(a)),

an isolated polypeptide containing an amino acid sequence having an identity of at least 95% to the amino acid sequence of SEQ ID NO: 4 (claim 7(b)), or

an isolated polypeptide containing amino acid sequence encoded by a polynucleotide capable of hybridizing to a polynucleotide having the nucleotide sequence of SEQ ID NO: 1 under stringent conditions (claim 7(c)).

Claim 14 is directed to a composition comprising the isolated polypeptide.

On the other hand, the sequences disclosed by Heidelberg have an identity of 85.4% to the amino acid sequence of SEQ ID NO: 4 and an identity of 75.7% to the nucleotide sequence of SEQ ID NO: 1.

The identity of 85.4% is of course clearly and significantly lower than 95% as recited in claim 7(b), and the polynucleotide having the identity of 75.7% does not hybridize to the sequence of SEQ ID NO: 1 under stringent conditions. Thus, the sequences disclosed in Heidelberg are clearly distinguished from the claimed sequences, and the polypeptide of claim 7 and the composition of claim 14 are novel.

Further, Heidelberg does not teach or suggest that degradation products of dsRNA function in RNA interference as a siRNA. Therefore, the polypeptide and the composition claimed in claims 7 and 14 are also unobvious from Heidelberg.

Withdrawal of the rejection is in order and is respectfully requested.

Claim 15 has been rejected under Section 102 as anticipated by Trotta et al, Reference V (Trotta). This rejection is respectfully traversed.

Claim 15 is directed to a kit comprising the polypeptide claimed in claim 7, and claim 15 thus incorporates the subject matter of claim 7.

The amino acid sequence of RNase III of *E. coli* disclosed by Trotta has an identity of 68.5% to the amino acid sequence of SEQ ID NO: 4 (see the attached Appendix I). This identity is of course considerably lower than 95% as claimed

in claim 7(b). Further, it does not hybridize with the polynucleotide of SEQ ID NO: 1 under stringent conditions. Therefore, the RNase III of *E. coli* disclosed by Trotta is not included in the polypeptide claimed in claim 7, and claim 15 is clearly novel over Trotta.

Further, as seen from Examples 5-9 disclosed in page 46, line 9 to page 61, line 12 (in particular, Tables 1-4) of the original English translation text, the polypeptide of the present invention can produce degradation products which function in RNA interference as an siRNA as compared with RNase III of *E. coli*. Therefore, the kit claimed in claim 15 is also unobvious over Trotta.

Withdrawal of the rejection is in order and is respectfully requested.

The prior art documents of record and not relied upon by the PTO have been noted, along with the implication that such documents are deemed by the PTO to be insufficiently material to warrant their application against any of applicants' claims.

Applicants believe that all issues raised in the Official Action have been addressed above in a manner that should lead to patentability of the present application.

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Favorable consideration and early formal allowance are
respectfully requested.

Respectfully submitted,

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